30043/JWE/A97

EFFICIENT ALGORITHM FOR PCR TESTING OF BLOOD SAMPLES

Cross-Reference to Related Applications

This application is a continuation-in-part of application No. 08/683,784, filed July 16, 1996, which is a division of application No. 08/419,620, filed April 10, 1995, the contents of which are expressly incorporated herein by reference.

Field of the Invention

The present invention relates generally to systems and processes for preparing and analyzing samples taken from plasma donations to uniquely identify donations which are virus contaminated. In particular, the invention relates to an apparatus and process for forming individual, separately sealed, and connected containers holding samples of the same plasma as is contained in the donation. The invention also relates to an apparatus and process for forming initial screening test pools from the containers and testing the pools for the presence of a virus in accordance with an algorithm to identify individual contaminated donations in the fewest number of testing cycles.

Background of the Invention

Blood, plasma, and biological fluid donation programs are essential first steps in the manufacture of pharmaceutical and blood products that improve the quality of life and that are used to save lives in a variety of traumatic situations. Such products are used for the treatment of immunologic disorders, for the treatment of hemophilia, and are also used in maintaining and restoring blood volume in surgical procedures and other treatment protocols. The therapeutic uses of blood, plasma, and biological fluids require that donations of these materials be as free as possible from viral contamination. Typically, a serology test sample from each individual blood, plasma, or other fluid donation is tested for various antibodies, which are elicited in response to specific viruses, such as hepatitis C (HCV) and two forms of the human immunodeficiency virus (HIV-1 and HIV-2). In addition, the serology test sample may be tested for antigens designated for specific viruses such as hepatitis B (HBV), as well as antibodies elicited in response to such viruses. If the sample is serology positive for the presence of either specific antibodies or antigens, the donation is excluded from further use.

Whereas an antigen test for certain viruses, such as hepatitis B, is thought to be closely correlated with infectivity, antibody tests are not. It has long been known that a blood plasma